§ 5.302 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), that relates to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f (b)) that relates to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 5.303 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director, Deputy Director, and Director of Regulations and Policy, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The delegation excludes the authority to submit reports to the Congress. These officials may not further redelegate this authority.

§ 5.304 Approval of schools providing food-processing instruction.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(b) These officials may not further redelegate this authority.

Subpart F—Medical Devices and Radiological Health; Redelegations of Authority

§ 5.400 Issuance of Federal Register documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Director and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to issue FEDERAL REGISTER documents under section 514(c) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360d(c)) recognizing or withdrawing recognition of a standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement.

(b) These officials may not further redelegate this authority.

§ 5.401 Issuance of Federal Register documents pertaining to exemptions from premarket notification.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Directors and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to make determinations and issue FEDERAL REGISTER notices and rules under § 510(m) of the act (21 U.S.C. 360(m)) concerning exemptions from premarket notification.

(b) These officials may not further redelegate this authority.

§ 5.402 Detention of adulterated or misbranded medical devices.

(a) The following officials are authorized to perform all the functions of the

Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)) and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(1) For medical devices assigned to their respective organizations:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(iv) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(b) These officials may not further redelegate this authority.

§ 5.403 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(a)(3)(B)) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act (21 U.S.C. 360c, 360d, and 360e):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Director, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(b) These officials may not further redelegate this authority.

§ 5.404 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f) and 360 j(1)) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (21 U.S.C. 360c(e)) (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under § 514(b) of the act (21 U.S.C. 360d(b)) or premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate this authority.

§ 5.405 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, under section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(d)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation